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Original Article

Protective effects of smoke-free legislation on birth outcomes in England; a regression discontinuity design.

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PROTECTIVE EFFECTS OF SMOKE-FREE LEGISLATION ON BIRTH OUTCOMES IN ENGLAND; A REGRESSION DISCONTINUITY DESIGN

ABSTRACT

Background: Environmental tobacco smoke has an adverse impact on preterm birth and birth weight. England introduced a new law to make virtually all enclosed public places and workplaces smoke free on July 1 2007. We investigated the effect of smoke-free legislation on birth outcomes in England using Hospital Episode Statistics (HES) maternity data.

Methods: We used regression discontinuity, a quasi-experimental study design, which can facilitate valid causal inference, to analyse short-term effects of smoke-free legislation on birth weight, low birth weight, gestational age, preterm birth and small for gestational age.

Results: We analysed 1,800,906 pregnancies resulting in singleton live-births in England between January 1 2005 and December 31 2009. In the one to five months following the introduction of the smoking-free legislation, for those entering their third trimester, the risk of low birth weight decreased by between 8% (95% CI: 4%-12%) and 14% (95% CI: 5%-23%), very low birth weight between 28% (95% CI: 19%-36%) and 32% (95% CI: 21%-41%), preterm birth between 4% (95% CI: 1%-8%) and 9% (95% CI: 2%-16%), and small for gestational age between 5% (95% CI: 2%-8%) and 9% (95% CI: 2%-15%). The impact of the smoke-free legislation varied by maternal age, deprivation, ethnicity and region.

Conclusions: The introduction of smoke-free legislation in England had an immediate beneficial impact on birth outcomes overall, although this benefit was not observed across all age, ethnic, or deprivation groups.

INTRODUCTION

England introduced comprehensive smoke-free legislation on July 1 2007, which prohibited smoking in all workplaces and enclosed public spaces. Numerous studies have documented the beneficial effects of the smoke-free legislation on a variety of health outcomes.[1, 2] To date, a limited number of studies worldwide have reported on the impacts of smoke-free legislation on adverse birth outcomes, including low birth weight (LBW), preterm delivery, and/or small for gestational age (SGA).[3-11]

Smoking is considered the single most important modifiable determinant of adverse birth outcomes. The birth weight of babies born to smokers is on average 150-250g lower than those of non-smokers.[7, 12] Maternal smoking is associated with a two-fold increased risk of intrauterine growth restriction and low birth weight.[7] A dose-response relationship is observed, with larger reductions in birth weight in heavy smokers and those who smoke during the last trimester (the period of peak fetal growth),[13] but even the lowest levels of maternal smoking have been shown to adversely impact birth weight.[12] Exposure to second-hand smoke has also been shown to have adverse effects on fetal growth and on subsequent infant morbidity and mortality.[14] LBW, preterm delivery, and SGA are important risk factors for neonatal morbidity and mortality[10] and have significant implications for future infant health[15-17] and on chronic conditions across the life course.[13, 17]

Making causal inference about the impact of large scale interventions, such as smoke-free legislation, based on interrupted time series models is limited given that extraneous factors may affect outcomes of interest and our inability to adjust for unmeasured confounding. Regression discontinuity (RD), a novel quasi-experimental design, can help overcome these issues and produce valid causal inferences, though this approach has to date found little application in epidemiology.[18-21]

The aim of this study was to determine the impact of the smoke-free legislation in England, introduced on July 1 2007, on birth weight, gestational age, and small for gestational age in England with the use of a novel RD design.

METHODS

Data

Data on pregnancies and birth outcomes for singleton live-births delivered at 24-44 weeks gestation between Jan 1 2005 and Dec 31 2009 in England were obtained from the Hospital Episodes Statistics (HES) maternity database, held by the UK Small Area Health Statistics Unit (SAHSU). This is an administrative database widely used for epidemiological and health services research and covers all births delivered in National Health Service (NHS) hospitals in England, capturing 87% of live births during our study period (when compared to legally notified birth registrations from the Office for National Statistics (ONS)).[22]

After removing duplicates, we excluded records with birth weight <200g, >5000g or unknown, with a gestational age of <24 week or >44 weeks,[5, 9] sex unknown and intersex infants, or with maternal age <15 or >44 years, in keeping with other studies.[23] Data quality checks identified anomalies in records provided by one primary care trust (1 out of 152 primary care trusts) and these records (n=11,439) were also excluded (Supplementary Digital Content 1).

Birth outcome variables

Our primary outcomes were birth weight, LBW (<2500g) and very low birth weight (VLBW)(<1500g),[24] gestational age, preterm birth (gestational-age at birth of less than 37 weeks),[24] and SGA (birth weight at delivery below the 10th centile for gestation (by sex),[25] using centiles derived from all eligible births).

Length of gestation was determined as the completed weeks of gestation according to the World Health Organization definition, which specifies time from the first day of the last menstrual period. If date of the last menstrual period is not available/reliable, an estimate is provided in the HES maternity database. We defined trimester 1 as weeks 0-13 and trimester 3 from week 27 to birth, calculated by counting back from gestational age at birth.

Effect modifiers

The following variables were obtained from the HES database: Maternal age (categorised into five groups: <20; 20-25; 26-29; 30-35; >35 years, based on previous studies);[5] infant sex; ethnicity of the mother (White, Black, South Asian, other).

The following variables were linked to each delivery via maternal postcode of residence at delivery: Government Office Region (GOR2001); Index of Multiple Deprivation (IMD) 2007, with IMD scores categorised into fifths (<8.3; ≥8.3-<13.74; ≥13.74-<21.22; ≥21.22-<34.42; ≥34.42), based on lower layer super output area quintiles across England. The IMD 2007 is a composite measure that provides a relative measure of deprivation at small area level across England and is based on seven domains of deprivation (income, employment, health and disability, education and skills, barriers to housing and services, crime, and living environment).[26]

Ethics

The study uses SAHSU data, supplied from the Office for National Statistics; data use was covered by approval from the National Research Ethics Service - reference 12/LO/0566 and 12/LO/0567 - and by Health Research Authority Confidentially Advisory Group (HRA-CAG) for Section 251 support (HRA - 14/CAG/1039); superseding National Information Governance Board and Ethics and Confidentiality Committee approval (NIGB - ECC 2-06(a)/2009).

Statistical Analysis

Regression discontinuity (RD)[27, 28] is a quasi-experimental design, which exploits a threshold rule data-generating process and creates comparable populations with different exposure statuses just above and below a threshold (here the introduction of smoke-free legislation, on the July 1 2007) also known as the ‘cut-off’ date. In the RD design, the exposure of interest is assigned by the value of a continuously measured random variable above (or below) some threshold value (here, date at entering the third trimester, relative to the cut-off date) and the threshold behaves like a randomising device. RD design does not measure the intervention effect as the difference in the averages of the outcome before and after the intervention for the whole time period of the study as in interrupted time series models, but measures the change, or discontinuity, in the effect before vs. after the intervention close to the cut-off point defined by the threshold value. The key feature of regression discontinuity design is the focus on comparing outcomes in a 'short' time interval before the intervention with a 'short' time interval after the intervention. By using these short time windows we can assume that no unobserved factors confound the relationship between the exposure and the outcome in that short time interval.

There are two types of RD design; a sharp regression discontinuity (SRD) design, applied when the probability of intervention assignment changes discontinuously at the cut-off date deterministically (from 0 to 1), and a fuzzy regression discontinuity (FRD) design, when the probability of intervention changes around the cut–off date stochastically. We can reasonably assume that after the implementation of the smoke free legislation all women received the intervention, because of high compliance (99%) of the policy in workplaces and restaurants by July 1 2007, but it is likely that some of the women received the intervention before the cut-off.[29] For example, anticipatory effects such as quitting behaviour have been documented which could have resulted in a reduction of active and passive smoking in the study population prior to policy implementation.[9] Since individual-level exposure to the benefits of the smoke-free legislation could not be taken into account, we used a FRD design to represent the intention-to-treat analysis of a fuzzy RD scenario. In addition, we omitted one month centred on the cut-off date of July 1 2007 (i.e. women entering their third trimester from June 15 2007 until July 15 2007 were excluded as they could belong either to the intervention or the control group).

All the conditions for a valid RD analysis were met:[19]

i) The decision rule (exposed or not exposed to the intervention) and cut-off value (July 1 2007) are known;

ii) The assignment variable (date of entering third trimester, measured in days) is continuous near the cut-off value and is not affected by the policy (see Figure, Supplemental Digital Content 2);

iii) Our outcomes are observed for all pregnancies and are continuous at the threshold, independent of whether mothers were exposed or not exposed to the smoke-free legislation intervention;

iv) Groups on either side of the cut-off are comparable with respect to pre-treatment covariates; observed factors (e.g. maternal age) are not discontinuous at the cut-off (see Figure, Supplemental Digital Content 3)

v) Visual confirmation of an intervention effect; graphical analysis (see Figure, Supplemental Digital Content 4-9) confirms the discontinuity, i.e. a visible jump at the cut-off value, indicating an intervention effect. These scatterplots suggest that a ‘fuzzy RD’ design is more appropriate.

For analytical purposes, we divided the sample into five cohort periods (2005, 2006, 2007, 2008, 2009) centred around the cut-off. The parameter of interest is the effect of policy on the birth outcome variable in the different time windows before versus after July 1 2007, relative to that observed before versus after July 1 in previous and subsequent years; these previous and subsequent cohorts in the model (years 2005, 2006, 2008, 2009) act as control periods to account for any existing temporal trends that occur every year around the cut-off date. This approach is strengthened by borrowing elements from a ‘difference-in-differences’ approach and is similar to a ‘differences in discontinuities’ design because it rests on the intuition of combining an RD design with a difference-in-differences strategy.[30] We estimated the policy effect on the outcome variable before versus after the cut-off using time windows of one, two, three and five months (shown schematically in Figure, Supplemental Digital Content 10). The wider the time window the more likely we are to capture the effects of smoke-free legislation on birth outcomes with greater statistical certainty due to larger numbers, but the more likely spurious variation due to potential temporal trends and unmeasured confounders will be introduced. In contrast to an interrupted time series model, the RD approach, by studying the before vs. after effect in shorter discrete time windows (e.g. of one to five months) around the cut-off date, allows us to exclude other interventions or known major influences on trends in birth outcomes occurring over the five year study period, and make the assumption that the only change is in relation to the intervention. A more detailed description of the FRD model is provided in the Supplemental Digital Content 11.

The FRD assumes comparability between the intervention and the control group,[31] meaning there is no need to adjust for potential confounders. Nonetheless, there may be heterogeneity in effect across important determinants of birth outcomes particularly due to maternal age, deprivation, and ethnicity and consequently subgroup analyses were performed and appropriate interaction terms were included in the models. A stratified analysis of the effect of smoke-free legislation on adverse birth outcomes was performed across Government Office Regions.

Sensitivity analyses

To assess the robustness of our results a series of sensitivity analyses were performed.

1) To check whether there was an immediate effect of smoke-free legislation on birth outcomes, we re-ran our analysis centred on the policy implementation (i.e. did not exclude one month centred on July 1 2007).

2) To check whether there was an extensive delayed effect of smoke-free legislation on birth outcomes, we re-ran our analysis omitting two months (from June 1 until July 31), centred on the policy implementation.

3) We applied different cut-off dates, January 1 2007 and April 1 2007, in order to capture potential anticipatory effects on smoking behaviours prior to the ban. Mackay et al (2012) provided evidence of anticipatory effects four months before the legislation came into force in Scotland.[9]

4) We assessed the impact of the smoke-free legislation on birth outcomes by assigning women to the intervention and control groups when they entered their first, rather than third trimester to assess if second hand smoke exposure was also important in the first trimester of pregnancy.

5) We also included an interaction term between the polynomial function of month and the different time windows to reduce the influence of time points further from the threshold and enable a consistent estimation of the conditional expectation function at the threshold.

All analyses were performed using STATA 13.1 (Stata Corporation, College Station, TX USA).

RESULTS

Compared to 3,112,333 singleton live-births in England with eligible birth weight, sex, and maternal age in ONS, we included 2,136,125 (68.4%) using our HES dataset. After further excluding records from a primary care trust with inaccurate data, those with gestational age of <24 week, >44 weeks, or gestational age unknown, 1,800,906 (57.6%) births remained. Data on these 1,800,906 live singleton births were therefore included in our analyses; maternal and infant characteristics are shown in Table 1.

Birth weight

FRD analyses showed a positive effect of the smoke-free legislation on birth weight for each time window (e.g. birth weights on average higher by 17.2 grams (95% CI: 5.7-28.7) and 19.4 grams

(95% CI: 13.7-25.1) in the one and five month window following policy implementation). We observed a protective effect on risk of LBW (ranging from OR: 0.86 (95% CI: 0.77-0.95) to 0.92 (95% CI: 0.88-0.96)) and VLBW (ranging from OR: 0.72 (95% CI: 0.54-0.97) to 0.72 (95% CI: 0.64-0.81) for the same time windows (Table 2).

Gestational age/preterm delivery/small for gestational age

FRD analyses showed a protective effect of smoke-free legislation on the risk of preterm birth ranging from OR: 0.91 (95% CI: 0.84-0.98) to 0.96 (95% CI: 0.92-0.99) and SGA ranging from OR: 0.91 (95% CI: 0.85-0.98) to 0.95 (95% CI: 0.92-0.98) across the different time windows following policy implementation. There was no change in gestational age following the smoke-free legislation (Table 2).

Influence of maternal age, deprivation, ethnicity and region

The impact of the smoke-free legislation varied by maternal age, ethnicity and deprivation. Reductions in risk of LBW and SGA were observed in the 20-25 years age group moving from the one to five month windows following policy implementation for LBW (ranging from OR: 0.83 (95% CI: 0.66-1.02) to 0.92 (95% CI: 0.84-0.99); and for SGA (ranging from OR: 0.76 (95% CI: 0.65-0.88) to 0.91 (95% CI: 0.85-0.97)) and in the 30-35 years age group for LBW (ranging from OR: 0.83 (95% CI: 0.62-1.02) to 0.89 (95% CI: 0.84-0.98)) (Figure 1). In addition, statistically significant interactions (p-values all <0.05) were observed between smoke–free legislation and maternal age for LBW across all four time windows.

There was evidence of statistical significant interactions between smoke-free legislation and ethnicity for LBW across the four time windows. There were no reductions in risk of any birth outcome across all four time windows in those of Black or South Asian ethnicity, but reductions in risk of LBW for those of White ethnicity (ranging from OR 0.84 (95% CI: 0.73-0.97) to 0.94 (95% CI: 0.89-0.99) across the four time windows) were observed (Figure 2).

There was also variability in risk by deprivation. Reductions in risk were observed across the four time windows for VLBW in quintile 2 (ranging from OR 0.37 (95% CI: 0.15-0.88) to OR 0.65 (95% CI: 0.46 -0.81)) and for LBW for quintile 4 (ranging from OR 0.74 (95% CI: 0.59-0.92) to 0.88 (95% CI: 0.80-0.96)) (Figure 3). Interaction terms between smoke-free legislation and deprivation were only statistically significant for VLBW across the four time windows (all p values < 0.05).

There was significant heterogeneity (p value of the I-square test <0.05) of the effect of smoke-free legislation on small for gestational age by Government Office Region. Compared to the country as a whole, more pronounced effects of the legislation were seen across the four time windows in East Midlands for LBW (ranging from OR 0.85 (95%CI: 0.63-0.98) to OR 0.79 (95% CI: (0.67-0.93)); in Yorkshire and Humber for LBW (ranging from OR 0.64 (95% CI: 0.43-0.95) to OR 0.89 (95% CI: 0.76-0.99)) and for SGA (ranging from OR 0.78 (95% CI: 0.60-0.99) to OR 0.96 (95% CI: 0.85-0.98)) (see Figure, Supplemental Digital Content 12-15).

No statistical significant interactions were observed between smoke-free legislation and region for any of the birth outcomes across the four-time windows.

Sensitivity analyses

With respect to the sensitivity analyses, similar associations (in terms of direction and magnitude of effect) were observed when:

1) We omitted no month (see Table, Supplemental Digital Content 16) or 2) two months, rather than one (see Table, Supplemental Digital Content 17) either side July 1 2007.

3) There was no evidence of an anticipatory effect when April 1 or January 1 2007 were considered as the cut-off months (data not shown).

4) When women were assigned to the intervention group on the basis of entering their first, rather than third trimester, there was no evidence of a consistent protective effect of the smoke free legislation on adverse birth outcomes (data not shown).

5) We added an interaction term of the polynomial function of month and the different time windows (see Table, Supplemental Digital Content 18).

DISCUSSION

This is the first study evaluating the short-term impact of the smoke-free legislation implemented on July 1 2007 in England on potentially preventable adverse birth outcomes (low birth weight, preterm delivery, and small for gestational age) using a novel approach, Regression Discontinuity design, that takes account of temporal and unmeasured trends and produces valid causal inference. Study findings indicated an increase in birth weight, and a reduction in the risk of low birth weight, very low birth weight, preterm birth, and small for gestational age in the months following implementation of the legislation, with a more pronounced effect in white ethnic groups and variability in effect by maternal age group and deprivation.

Here we report on a natural experiment. Assignment to the intervention group in the regression discontinuity design is not random, although individuals are assigned to the intervention group on the basis of a continuously measured cut-off score (date at entering their third trimester), which the individuals cannot precisely manipulate. Assignment is therefore assumed to be quasi-random for observations close to the cut-off, allowing valid causal effects to be identified.[18] The regression discontinuity approach employed here can be a powerful method to aid causal inference in circumstances in which there is a known time point where a population is affected by a policy or intervention. Previous literature employed standard interrupted time series models to evaluate the effect of smoke free legislation on adverse birth outcomes[5, 8, 9]. These standard interrupted time series models could potentially lead to biased estimates due to unmeasured confounding, lack of appropriate control groups, ecological bias, and underlying temporal trends in birth outcomes over the study period.

Compared to previous literature, our regression discontinuity model for a two-month interval detected similar effects to a recent meta-analysis of the effect of smoke-free legislation for preterm birth (9% vs 10.4%)[11] and a recent retrospective cohort study for low birth weight (13% vs 9.9%) and small for gestational age (6% vs 4.5% reduction in risk post-legislation). [9] We found a more pronounced effect for very low birth weight (29% vs 1.9% reduction in risk post-legislation)[4]

The observed decreased risk of preterm birth and low birth weight are biologically plausible, supported by a report which concluded there was suggestive/sufficient evidence of a causal relationship between environmental tobacco smoke and preterm delivery/low birth weight respectively[32]. Although our estimates for a reduction in risk of very low birth weight are larger than previously reported in observational studies,[3, 4] a beneficial effect is plausible, supported by a recent randomized controlled trial where the rates of very low birth weight were significantly reduced in infants born to mothers with reduced environmental tobacco exposure.[33] We recommend future studies include very low birth weight as an outcome, to add to the currently limited evidence base.

Our findings suggest some evidence of variability on the effects of the policy by deprivation quintile, however there was no consistent evidence of inequality. Other studies have shown a greater reduction of second-hand smoke exposure in children of more affluent backgrounds compared to children of less affluent backgrounds after introduction of the smoke-free legislation.[34, 35]

There are limitations to our study. Birth registration is a legal requirement under the Births and Deaths Registration Act 1836, and the ONS birth statistics represent a legal record, making it the best and most complete data source.[36] However, ONS birth statistics do not include gestational age so we used HES maternity data for this study. Our final HES based dataset contained only 58% of eligible births recorded by ONS over the study period, potentially introducing bias into our analysis. However, the HES dataset has similar maternal age distribution as ONS birth statistics, and a similar distribution of deprivation (unpublished observations). Ethnicity is not included in ONS birth statistics, but a linkage study reported that the baby's ethnicity recorded in the NHS Numbers for Babies (NN4B) record and the mother's ethnicity recorded in Maternity HES showed agreement in three quarters of the records which had a stated ethnic category.[37] It is also reassuring that our findings are similar in magnitude and direction to previous studies assessing the impact of smoke-free legislation on birth outcomes, suggesting bias is unlikely to explain our findings. Our ability to assess the modifying effect of deprivation and ethnicity on the association between the legislation and birth outcomes was likely impacted by missing data, 7.9% and 11.3% of births were missing deprivation (because postcodes were unable to be geocoded) and ethnicity data respectively. There was no evidence for differential reporting of these characteristics, e.g. birth weight, gestational age and maternal age did not significantly differ between births with and without these covariate data. HES data do not include data on maternal smoking status and on other known maternal (stress, weight) and environmental exposures (air pollution, nutrition) although this is a common problem to most studies evaluating the effect of smoke-free legislation on adverse birth outcomes.[11] However, with the use of regression discontinuity design and appropriate time windows, we minimised the impact of potential unmeasured confounders. Despite including more than one and a half million singleton live-births, when stratifying by maternal age, deprivation, ethnicity and government office region, some effect estimates became non-significant due to potential issues of statistical power.

Recent studies have emphasized that observational studies should, where possible, be carefully designed to approximate randomized experiments. RD designs can aid causal inference over traditional observational studies, can be utilised to establish causal effects where RCTs cannot be ethically conducted, and can evaluate the real-world effectiveness of a policy or intervention.

The WHO Framework Convention on Tobacco Control (FCTC) recommends that countries eliminate smoking from public places,[38] yet only 18% of the global population are covered by comprehensive smoke-free policies. This study, along with previous work, presents clear and crucial evidence showing the reduction in adverse birth outcomes due to the implementation of smoke-free legislation. In the context of the ongoing burden of adverse birth outcomes in Low and Middle Income Countries, with perinatal conditions, including low birth weight and prematurity, responsible for 6% global DALYs among children aged 0-4 years,[39] these findings indicate that smoke-free legislation may help countries achieve improved child health, addressing the Millennium Development Goal 4, to reduce by two thirds, between 1990 and 2015, the under-five mortality rate.

SUPPLEMENTAL DIGITAL CONTENT

- Supplemental Digital Content 1: Supplemental Digital Content 1: Flow diagram presenting the cohort creation, exclusions and the final sample size.
- Supplemental Digital Content 2: Histogram of assignment variable, demonstrating that the date of entering third trimester is continuous near the cut-off value and is not affected by the policy.
- Supplemental Digital Content 3: Daily average maternal age plotted against the assignment variable (day of 3rd trimester) to demonstrate comparability of pre-treatment covariates at the cut-off.
- Supplemental Digital Content 4: Daily average birth weight plotted against the assignment variable (day of 3rd trimester) to demonstrate discontinuity at the cut-off value.
- Supplemental Digital Content 5: Daily average gestational age plotted against the assignment variable (day of 3rd trimester) to demonstrate discontinuity at the cut-off value..
- Supplemental Digital Content 6: Daily percentage of low birth weight plotted against the assignment variable (day of 3rd trimester) to demonstrate discontinuity at the cut-off value..
- Supplemental Digital Content 7: Daily percentage of very low birth weight plotted against the assignment variable (day of 3rd trimester) to demonstrate discontinuity at the cut-off value.
- Supplemental Digital Content 8: Daily percentage of preterm delivery plotted against the assignment variable (day of 3rd trimester) to demonstrate discontinuity at the cut-off value.
- Supplemental Digital Content 9: Daily percentage of small for gestational age plotted against the assignment variable (day of 3rd trimester) to demonstrate discontinuity at the cut-off value.

- Supplemental Digital Content 10: Schematic timeline diagram presenting the date of introduction of the smoke-free legislation and the different time windows considered in the fuzzy regression discontinuity analysis.
- Supplemental Digital Content 11: Detailed description of estimation using our FRD design.
- Supplemental Digital Content 12: Effect of the smoke-free legislation on birth outcomes stratified by region, 1-month window.
- Supplemental Digital Content 13: Effect of the smoke-free legislation on birth outcomes stratified by region, 2-month window.
- Supplemental Digital Content 14: Effect of the smoke-free legislation on birth outcomes stratified by region, 3-month window.
- Supplemental Digital Content 15: Effect of the smoke-free legislation on birth outcomes stratified by region, 5-month window.
- Supplemental Digital Content 16: Effect of the smoke-free legislation on birth outcomes before and after July 1 2007 (i.e. omitting no month).
- Supplemental Digital Content 17: Effect of the smoke-free legislation on birth outcomes before and after June 1 2007 - July 31 2007 (i.e. omitting two months).
- Supplemental Digital Content 18: Effect of the smoke-free legislation on birth outcomes before and after June 15 2007 - July 15 2007, including an interaction term between the polynomial function of month and time windows.

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TABLE 1. Descriptive Statistics for births included in the analysis (n=1,800,906)			
Characteristics	**Total**	**%**	**Median (10^{th} – 90^{th} centile)**
Birth outcomes			
Birth weight (grams)	1,800,906	100	3380 (2700-4030)
Very Low birth weight	14,517	0.81	-
Low birth weight	102,006	5.66	-
Gestational age (weeks)	1,800,906	-	40 (37-41)
Preterm Birth	126,527	7.03	-
Small for gestational age	175,940	9.77	-
Sex of baby	1,800,906		
Female	885,328	49.1	-
Male	915,578	50.8	-
Maternal Age	1,800,906		
16-20 (0)	174,426	9.6	-
20-25 (1)	381,736	21.2	-
26-29 (2)	504,848	28.0	-
30-35 (3)	470,137	26.1	-
>35-44 (4)	269,759	14.9	-
Region	1,793,119	99.5	
Missing	7,787	0.5	
North East	78,652	4.3	-
North West	247,827	13.7	-
Yorkshire and Humber	162,949	9.0	-
East Midlands	143,720	7.9	-
West Midlands	204,582	11.3	-
East of England	196,625	10.9	-
London	371,630	20.6	-
South East	225,941	12.5	-
South West	161,193	8.9	-
Ethnicity	1,597,430	88.7	
Missing	203,476	11.3	
White	1,214,893	67.4	-
Black	113,458	6.3	-
Asian	162,459	9.0	-
Other	106,620	5.9	-
Deprivation (quintiles)	1,658,672	92.1	
Missing	142,234	7.9	
0 (least deprived)	239,802	14.4	-
1	253,822	15.3	-
2	295,051	17.7	-
3	368,390	22.2	-
4 (most deprived)	501,607	30.2	-

TABLE 2. Effect of the smoke-free legislation on birth outcomes; birth weight, gestational age, low birth weight, very low birth weight, preterm birth and small for gestational age; different time windows before and after June 15 2007 - July 15 2007 (1- month window, 2- month window, 3– month window and 5- month window). Mean Difference, Odds Ratio (ORs) and 95% confidence intervals were estimated with the use of fuzzy regression discontinuity design for women entering their third trimester around the cut-off date of July 1 2007.

	Exposure window			
	omit one month ± one month	omit one month ± two months	omit one month ± three months	omit one month ± five months
	mean difference (95%CI) p-value	mean difference (95%CI) p-value	mean difference (95%CI) p-value	mean difference (95%CI) p-value
N	321,414	620,661	922,337	1,508,187
birth weight (g)	17.23 (5.73-28.74) 0.003	18.70 (9.99-27.41) <0.001	19.90 (12.64-27.15) <0.001	19.41 (13.67-25.14) <0.001
gestational age (weeks)	0.01 (-0.02-0.02) 0.726	0.02 (-0.02-0.05) 0.421	0.02 (-0.02-0.04) 0.516	0.02 (-0.01-0.04) 0.093
	OR (95%CI) p-value	OR (95%CI) p-value	OR (95%CI) p-value	OR (95%CI) p-value
low birth weight	0.86 (0.77-0.95) 0.004	0.87 (0.81-0.94) <0.001	0.88 (0.83-0.93) <0.001	0.92 (0.88-0.96) <0.001
very low birth weight	0.72 (0.54-0.97) 0.029	0.71 (0.59-0.86) <0.001	0.68 (0.59-0.79) <0.001	0.72 (0.64-0.81) <0.001
preterm birth	0.95 (0.83-0.99) 0.030	0.91 (0.84-0.98) <0.001	0.94 (0.89-0.99) 0.020	0.96 (0.92-0.99) 0.048
small for gestational age	0.91 (0.85-0.98) 0.01	0.94 (0.89-0.99) 0.024	0.93 (0.89-0.97) <0.001	0.95 (0.92-0.98) <0.001

Sources: HES data on pregnancies.

All RD models are adjusted for maternal age, cohort (2005, 2006, 2007, 2008, 2009), an interaction term of maternal age and cohort and an age-specific function of month within the cohort.

FIGURE 1. Effect of the smoke-free legislation on adverse birth outcomes; low birth weight (LBW), very low birth weight (VLBW), preterm birth (Preterm), and small for gestational age (SGA) stratified by maternal age (age groups: <20, 20-25, 26-29, 30-35, >35); different time windows before and after June 15 2007 - July 15 2007 (1- month window, 2- month window, 3–month window and 5- month window); Odds Ratio (ORs) and 95% confidence intervals were estimated with the use of fuzzy regression discontinuity design.

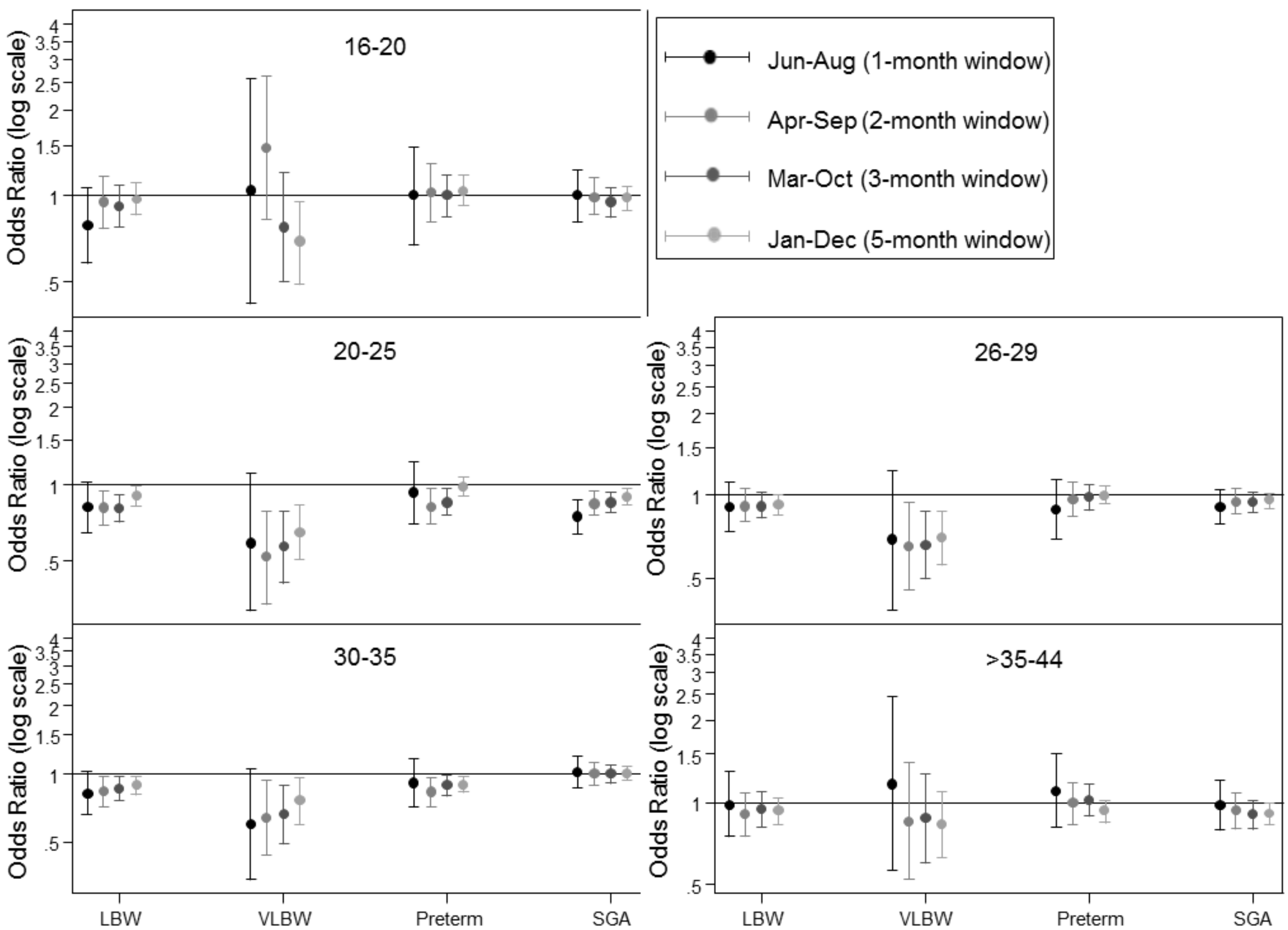

FIGURE 2. Effect of the smoke-free legislation on adverse birth outcomes; low birth weight (LBW), very low birth weight (VLBW), preterm birth (Preterm) and small for gestational age (SGA) stratified by ethnic origin (White, Black, and South Asian); different time windows before and after June 15 2007 - July 15 2007 (1- month window, 2- month window, 3– month window and 5- month window); Odds Ratio (ORs) and 95% Confidence intervals were estimated with the use of fuzzy regression discontinuity.

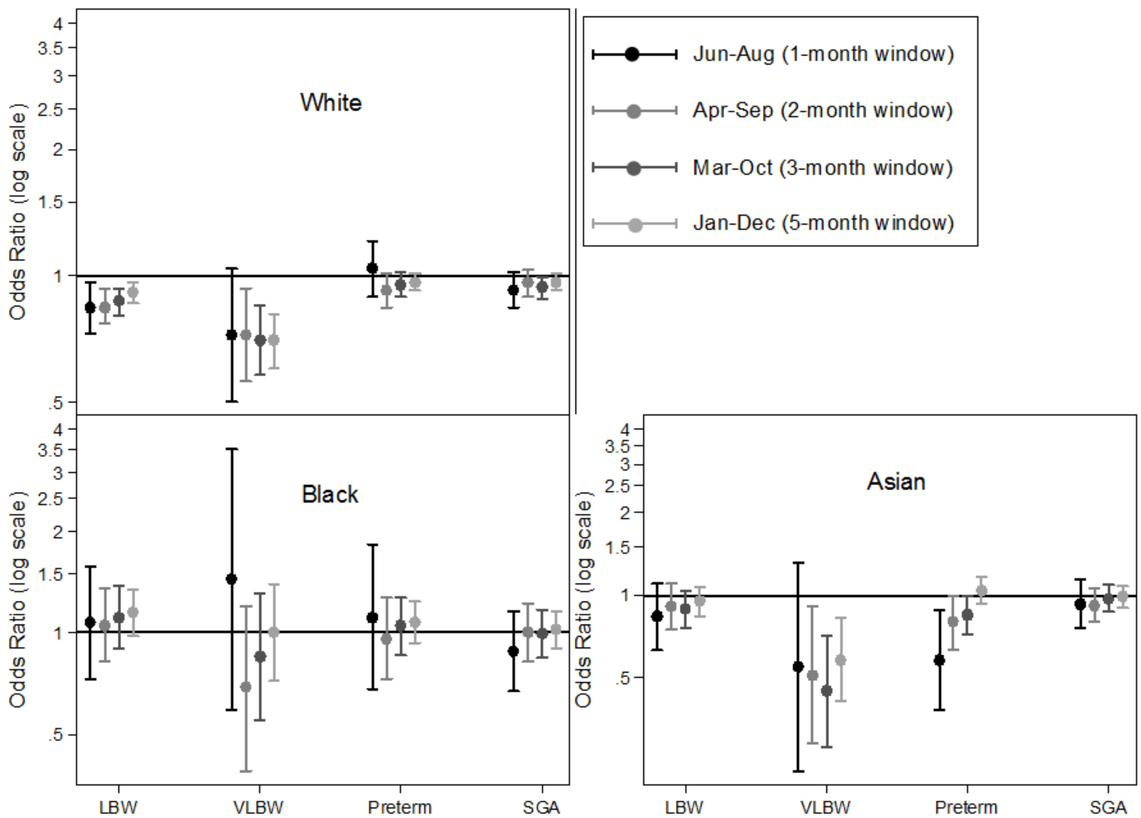

FIGURE 3. Effect of the smoke-free legislation on adverse birth outcomes; low birth weight (LBW), very low birth weight (VLBW), preterm birth (Preterm) and small for gestational age (SGA) stratified by socio-economic status (IMD deprivation 2007 score: quintile 1 (Q1) represents the least deprived neighbourhoods of the mothers residence and quintile 5 (Q5) represents the most deprived); different time windows before and after June 15 2007 – July 15 2007 (1- month window, 2- month window, 3– month window and 5- month window); Odds Ratio (ORs) and 95% Confidence intervals were estimated with the use of fuzzy regression discontinuity design.